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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,750	10/25/2001	Jenny Louie-Helm	3100-0003	1055

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,750	LOUIE-HELM ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40 and 45-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40 and 45-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/05/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of declaration under 37 CFR 132 and amendment filed 02/05/04. Claims 41-44 are cancelled. New claims 45-54 are added. Claims 1-40 and 45-54 are pending.

Observation/Suggestion:

Applicants refer to the fact that the term "cellulosic" is disclosed in the specification. The observation is not that the term "cellulosic" is not disclosed but rather than the term includes elements that are not disclosed by the term. It is still suggested that the term ---cellulose--- be used in place of "cellulosic." What celluloses are included in the term cellulosic."

Claim Rejections - 35 USC § 102

1. Claims 1-9, 12-16, 18-23, 26-34, 36-40 and 45-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Shell et al. (US 5,972,389).

Shell discloses a controlled release oral dosage form that comprises drug particles dispersed in swellable/erodible polymer where the erodible polymer is polyethylene oxide; the dosage form is formulated as tablet or capsule and liposomes or nanoparticles or enteric-coated drug particles are examples of drug containing vesicles that can deliver drugs to the site of interest (abstract, column 1, line 48 to column 2 line 36, column 3, lines 26-44, column 4, lines 5-18, column 7, lines 60-62, column 8, lines 4-55). Ciprofloxacin (column 5, line 10), bismuth subsalicylate, bismuth citrate, antibiotics such as amoxicillin, tetracycline, chlarithromycin, thiamphenicol, metronidazole which are Helicobacter pylori eradicating drugs (column 5, lines 46-49 and claims 6-9), gastric lowering agents such as omeprazole, ranitidine, cimetidine, famotidine (column 5, lines 49-55) are examples of drugs delivered by the dosage form of Shell.

Shell also teaches that nifedipine, acyclovir, alprazolam, phenytoin, carbamazepine, clozapne, lovastatin and nitrofurantoin are other drugs that can be delivered by the vesicle (claim 5).

The molecular weight of the polyethylene glycol in Shell ranges from 1 X 10^5 to 7 X 10^6 kD (claims 3 and 4). The weight ratio of drug to polymer is 2:3 to 9:1 (column 8, lines 26-31).

Claims 2-5 are directed to the property of the dosage and since a property of a composition is not separable from the composition, and in this case the dosage form, Shell meets scope of the limitations of the claims. Claim 1 is a dosage form that comprises a pharmacologically active agent and hydrophilic polymer. In claim 9, the presence of a mixture of polyethylene oxide-co-propylene oxide is optional so that Shell meets the limitation of claims 1. Shell teaches a range of drug to polymer and one of the points in the taught range in Shell anticipates a point in the recited range in claims 13-16. The solubility of the active agent at the designated temperature is a property of the active agent and since no specific active agent is recited, Shell meets the limitations of the claims. Also the molecular weight of the active agent is a property of the active agent and because the instant claims have not recited any drugs that would have the molecular weight recited in instant claim 21 and because some of the drugs recited in the claims are the same as those taught by Shell, Shell meets the limitations of claim 21. Therefore, the teachings of Shell meet the limitations of the claims.

Applicants argue that the instant claim 1 is directed to controlled release dosage form for administering pharmacologically active agent to the stomach, duodenum, and upper intestine of a patient ..., the prior art does not teach or suggest the use of a test, such as disintegration test, to optimize the disclosed oral dosage form for improved delivery of the drug in the stomach, duodenum, or the upper gastrointestinal tract.

2. Applicants' arguments filed 02/05/04 have been fully considered but they are not persuasive.

Disintegration is a property of the dosage form and optimization for improved drug delivery has no patentable weight in a composition claim. Applicants are aware that the molecular weight of the polyethylene oxide in Shell is 900,000 to about 8,000,000, with example 7, specifically disclosing a molecular weight of 2,000,000 for polyethyleneoxide and this molecular weight meets the limitations of claims 50-53.

3. Claims 1-7, 10, 12, 17-23 and 45-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Shell (US 5,007,790).

Shell discloses a sustained release oral dosage form in tablet or pill and the dosage form comprises drugs and cross-linked hydrophilic and water swellable polymer (abstract, column 2, line 29 to column 3 line 15 and claims 1-9). The drugs included in the dosage form of Shell are calcium carbonate, cimetidine, ranitidine, indomethacin, ibuprofen, naproxen, prednisone, prednisolone, dexamethasone, piroxicam, aspirin, nifedipine and potassium chloride potassium supplement (column 2, lines 28-35); carboxymethyl cellulose, alginate, polyvinyl alcohol and chitin (column 3, lines 7-16) are examples of cross-linked polymer.

Claims 2-5 are directed to the property of the dosage and since a property of a composition is not separable from the composition, and in this case the dosage form, Shell meets scope of the limitations of the claims. Claim 1 is a dosage form that comprises a pharmacologically active agent and hydrophilic polymer. The solubility of the active agent at the designated temperature is a property of the active agent and since no specific active agent is recited, Shell meets the limitations of the claims. Claims 45-49 recite the properties and how to

optimize the composition, which are not critical to a composition. Also the molecular weight of the active agent is a property of the active agent. Shell reads on the scope of the claims.

Applicants argue that Shell dos not teach or disclose that the dosage form may be optimized through the use of disintegration test and thus the Shell reference does not anticipate or render obvious claims 1-7, 10, 12, 17-23 and new claims 45-54.

4. Applicants' arguments filed 02/05/04 have been fully considered but they are not persuasive. Optimization of the dosage form through disintegration test is not given patentable weight because it is the composition that is claimed and that must be taught.

5. Claims 1-7, 10, 17-22 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Uemura et al. (US 4,695,467).

Uemura discloses sustained release tablet; the tablet comprising disintegrable granules that contain a drug, disintegrating agents selected from starch derivatives, gums, cellulose derivatives and ion exchange resins, and water soluble polymer selected from cellulose derivatives, synthetic water soluble polymers and polysaccharide and excipient (abstract, column 3, lines 10-21). The water-soluble cellulose derivatives are hydroxypropylmethylcellulose, methylcellulose, hydroxypropylcellulose and carboxymethylcellulose; synthetic water-soluble polymers are polyvinylpyrrolidone, cross-linked polyvinylpyrrolidone and polyethylene oxide; and pullulan and dextran are examples of polysaccharides (column 3, lines 33-41).

Claims 2-5 are directed to the property of the dosage and since a property of a composition is not separable from the composition, and in this case the dosage form, Shell meets scope of the limitations of the claims. Claim 1 is a dosage form that comprises a pharmacologically active agent and hydrophilic polymer. The solubility of the active agent at the designated temperature

is a property of the active agent and since no specific active agent is recited and the molecular weight of the active agent is a property of the active agent. The teaching of Uemura meets the limitations of the claims.

Applicants argue that Uemura is not enabled for a polyethylene oxide having a molecular weight of 2,000,000 as recited new claim 50.

6. Applicants' arguments filed 02/05 have been fully considered but they are not persuasive. New claim 50 is not included in the rejection under 35 USC 102.

7. The rejection of claims 1-25, 39 and 40 under 35 U.S.C. 102(e) as being anticipated by is withdrawn in light of the 37 CFR 1.132 declaration.

8. Claims 1, 6-8, 10, 11, 23, 24, 25, 30, 34 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Vandecruys et al. (US 6,667,069).

Vandecruys discloses a controlled release matrix formulation that comprises xanthan gum, hydroxypropylmethyl cellulose or polyethylene oxide in the matrix (abstract, column 9, line 19 and 31) and metformin antidiabetic agent (column 5, line 65), topiramate anti-epileptic drug (column 6, line 2) or paclitaxel (column 6, line 19) as some of the active agent in the matrix. Xanthan gum is a swellable polymer. Vandecruys meets the limitations of the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600